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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,967	05/04/2001	Emanuel Calenoff	21417/92378	6936
23644	7590	11/18/2003	EXAMINER	
BARNES & THORNBURG			CHEU, CHANGHWA J	
P.O. BOX 2786			ART UNIT	
CHICAGO, IL 60690-2786			PAPER NUMBER	
			1641	
			DATE MAILED: 11/18/2003	

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/848,967

Applicant(s)

CALENOFF ET AL.

Examiner

Jacob Cheu

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 4-16 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 17-19, 21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10. 6) ☐ Other: _____

Art Unit: 1641

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I, claims 1-3, 17-19 and 21-22, in Paper No. 14 is acknowledged. Accordingly, non-elected claims 4-16, 20 are withdrawn from further consideration.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-3, 17-19, 21-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, item (d), "on a comparative protein" is vague, indefinite and confusing. It is unclear what constitutes "comparative protein." It is unclear what constitutes "comparative proteins."

With respect to claim 1, item (f), "an antigenic profile" is vague and indefinite. It is unclear what is the "antigenic profile". Applicant needs to clarify.

With respect to claim 20, line 4, "administered to the cells of an individual" is vague and indefinite. It is unclear what cells applicant refers to.

With respect to claim 20, "administered to the cells of an individual" is vague and indefinite. It is unclear whether the "administering" is conducted "in vivo" or "in vitro".

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Barry et al. (JBC 1994 269: 8488-8492).

Barry et al. teach a peptide, i.e. human interleukin IL-3, its hydrophilic region containing Asp²¹, Glu²², and Thr²⁵, are crucial for IL-3 biological functions. (See abstract) Barry et al. aligned two “comparative peptides”, e.g. segments of IL-5 and GM-CSF, to predict the functionality of the IL-3 in receptor binding. (See Figure 1, page 8489, Result section, first paragraph) The sequence homology between the target IL-3 and GM-CSF or IL-3 and IL-5 is less than 50%. Furthermore, no more than 3 contiguous amino acid homology appears between IL-3 versus GM-CSF or IL-5. (See Figure 1) IL-3 has been shown capable of eliciting various immunological functions, including leukocyte adhesion, enhancement of releasing histamine from basophils, and increasing transmigration of leukocyte to sites of inflammation which are inherently involving anti-microbial activities and are useful for anti-microbial therapeutics. (See page 8488, left column, first paragraph to page 8488, right column, first paragraph)

6. Claims 1-3, 17, 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Regenmortel (ASM News 1998 64: 332-338).

Regenmortel teaches developing synthetic peptides by algorithms predictions. Regenmortel disclose the mimotopes peptides where those peptides can bind to the target molecules but do not share sequence similarity with the target protein on the cell surface. (page 334, right column, third paragraph) Some of the mimotopes examples illustrated in Figure 4 where HbsAg and Mimotopes 13 only share 20% homology (T and C), and less

Art Unit: 1641

than 3 contiguous amino acid in the sequence. Regenmortel also teaches that the prediction calculations are based on 20 amino acid residues which containing properties of hydrophilicity and associated with antigenicity. (page 337, right column, first paragraph)

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Regenmortel in view of Hasegawa et al. (US 4606857).

Regenmortel teach using recombinant technique, e.g. phage library, to synthesize peptides capable of producing immunogenicity to combat viral infection. (page 334-336)
However Regenmortel does not explicitly teach coupling the selected peptides with an

Art Unit: 1641

adjuvant molecule to enhance immunogenicity of the peptide. Hasegawa et al. teach coupling a muramyl molecule to a peptide to enhance immunogenicity reaction. (See formula I, and col. 1, line 32-42) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Regemortel with the adjuvant molecule as taught by Hasegawa et al. to increase the efficacy of immunogenicity since it is well-known and common practice in the art to couple adjuvant molecule with the peptides for enhancement of immunogenicity.

10. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Regemortel in view of Tu et al. (US 5674483).

Regemortel reference has been discussed but is silent in teaching prescribing the peptide as a desensitizing agent for therapy purposes. Tu et al. teach a method of administering IL-2 in an effective amount to desensitize airway hyperactivity and subsequently prescribing IL-2 increasingly to induce immune tolerance to the specific respiratory antigens. (Col. 2, line 15-45) Tu et al. reveal that this method provides the advantages of less side effects and less toxicity. (Col. 2, line 1-10) Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the peptides of Regemortel with the desensitizing method as taught by Tu et al. since it is well-known in the art to reduce the immune tolerance, and decrease side effects and toxicity.

Conclusion

11. No claim is allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 703-306-4086. The examiner can normally be reached on 9:00-5:00.

Art Unit: 1641

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone number for the organization where this application or proceeding is assigned is 703-746-9434.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-305-3399.

Jacob Cheu

Examiner

Art Unit 1641

November 14, 2003



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

11/14/03